

# Notice of Allowability

Application No.

10/719,150

Examiner

Michael Brannock

Applicant(s)

TRACEY ET AL.

Art Unit

1649

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address--

All claims being allowable, PROSECUTION ON THE MERITS IS (OR REMAINS) CLOSED in this application. If not included herewith (or previously mailed), a Notice of Allowance (PTOL-85) or other appropriate communication will be mailed in due course. **THIS NOTICE OF ALLOWABILITY IS NOT A GRANT OF PATENT RIGHTS.** This application is subject to withdrawal from issue at the initiative of the Office or upon petition by the applicant. See 37 CFR 1.313 and MPEP 1308.

1. ☒ This communication is responsive to that received 11/3/2006.

2. ☒ The allowed claim(s) is/are 1-28.

3. ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a) ☐ All b) ☐ Some\* c) ☐ None of the:

1. ☐ Certified copies of the priority documents have been received.

2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.

3. ☐ Copies of the certified copies of the priority documents have been received in this national stage application from the International Bureau (PCT Rule 17.2(a)).

\* Certified copies not received: \_\_\_\_\_.

Applicant has THREE MONTHS FROM THE "MAILING DATE" of this communication to file a reply complying with the requirements noted below. Failure to timely comply will result in ABANDONMENT of this application.

**THIS THREE-MONTH PERIOD IS NOT EXTENDABLE.**

4. ☐ A SUBSTITUTE OATH OR DECLARATION must be submitted. Note the attached EXAMINER'S AMENDMENT or NOTICE OF INFORMAL PATENT APPLICATION (PTO-152) which gives reason(s) why the oath or declaration is deficient.

5. ☐ CORRECTED DRAWINGS (as "replacement sheets") must be submitted.

(a) ☐ including changes required by the Notice of Draftsperson's Patent Drawing Review (PTO-948) attached

1) ☐ hereto or 2) ☐ to Paper No./Mail Date \_\_\_\_\_.

(b) ☐ including changes required by the attached Examiner's Amendment / Comment or in the Office action of Paper No./Mail Date \_\_\_\_\_.

Identifying indicia such as the application number (see 37 CFR 1.84(c)) should be written on the drawings in the front (not the back) of each sheet. Replacement sheet(s) should be labeled as such in the header according to 37 CFR 1.121(d).

6. ☐ DEPOSIT OF and/or INFORMATION about the deposit of BIOLOGICAL MATERIAL must be submitted. Note the attached Examiner's comment regarding REQUIREMENT FOR THE DEPOSIT OF BIOLOGICAL MATERIAL.

## Attachment(s)

1. ☐ Notice of References Cited (PTO-892)

2. ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)

3. ☒ Information Disclosure Statements (PTO/SB/08),  
Paper No./Mail Date 2/10/06

4. ☐ Examiner's Comment Regarding Requirement for Deposit of Biological Material

5. ☐ Notice of Informal Patent Application

6. ☐ Interview Summary (PTO-413),  
Paper No./Mail Date \_\_\_\_\_.

7. ☒ Examiner's Amendment/Comment

8. ☐ Examiner's Statement of Reasons for Allowance

9. ☐ Other \_\_\_\_\_.

  
JANET L. ANDRES  
SUPERVISORY PATENT EXAMINER

Art Unit: 1649

### EXAMINER'S AMENDMENT

An examiner's amendment to the record appears below. Should the changes and/or additions be unacceptable to applicant, an amendment may be filed as provided by 37 CFR 1.312. To ensure consideration of such an amendment, it MUST be submitted no later than the payment of the issue fee.

Authorization for this examiner's amendment was given in a telephone interview with Kristin Connarn on 12/14/2006.

The application has been amended as follows:

*C.A.* In claims 4, 8, 12, 16, 20, 24 and 28 please delete the following: (IL-1ra)

### *Conclusion*

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Michael Brannock, Ph.D., whose telephone number is (571) 272-0869. The examiner can normally be reached on Mondays through Fridays from 10:00 a.m. to 4:00 p.m. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Janet Andres, Ph.D., can be reached at (571) 272-0867. Official papers filed by fax should be directed to **571-273-8300**.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the Group receptionist whose telephone number is (703) 308-0196.

MB



12/22/2006

**Amendments to the Claims**

Please amend Claims 1, 2, 5, 6 and 9. Please add new Claims 13-28. The Claim Listing below will replace all prior versions of the claims in the application:

**Claim Listing**

1. (Currently Amended) A method for treating a condition characterized by activation of the inflammatory cytokine cascade, comprising administering an effective amount of an ~~antagonist or inhibitor of HMG1~~ antagonist effective to inhibit the inflammatory cytokine cascade, wherein said HMG1 antagonist is an antibody that binds to HMG1 and inhibits the interaction between HMG1 and RAGE.
2. (Currently Amended) The method of Claim 1 further comprising administering a second agent in combination with the ~~antagonist or inhibitor of HMG1~~ antagonist, wherein the second agent is an antagonist of an early sepsis mediator.
3. (Original) The method of Claim 2 wherein the second agent is an antagonist of a cytokine selected from the group consisting of TNF, IL-1 $\alpha$ , IL-1 $\beta$ , MIF and IL-6.
4. (Original) The method of Claim 3 wherein the second agent is an antibody to TNF or an IL-1 receptor antagonist ~~(IL-1ra)~~.
5. (Currently Amended) A method for treating sepsis ~~and related conditions involving activation of the inflammatory cytokine cascade~~, comprising administering an effective amount of an ~~antagonist or inhibitor of HMG1~~ antagonist effective to inhibit the inflammatory cytokine cascade, wherein said HMG1 antagonist is an antibody that binds to HMG1 and inhibits the interaction between HMG1 and RAGE.

6. (Currently amended) The method of Claim 5 further comprising administering a second agent in combination with the ~~antagonist or inhibitor of HMG1~~ antagonist, wherein the second agent is an antagonist of an early sepsis mediator.
7. (Original) The method of Claim 6 wherein the second agent is an antagonist of a cytokine selected from the group consisting of TNF, IL-1 $\alpha$ , IL-1 $\beta$ , MIF and IL-6.
- E.A. 8. (Original) The method of Claim 7 wherein the second agent is an antibody to TNF or an IL-1 receptor antagonist (~~IL-1ra~~).
9. (Currently Amended) A method for treating rheumatoid arthritis, comprising administering an ~~effective~~ amount of an ~~antagonist or inhibitor of HMG1~~ antagonist effective to inhibit the inflammatory cytokine cascade, wherein said HMG1 antagonist is an antibody that binds to HMG1 and inhibits the interaction between HMG1 and RAGE.
10. (Original) The method of Claim 9 further comprising administering a second agent in combination with the HMG1 antagonist, wherein the second agent is an antagonist of an early sepsis mediator.
11. (Original) The method of Claim 10 wherein the second agent is an antagonist of a cytokine selected from the group consisting of TNF, IL-1 $\alpha$ , IL-1 $\beta$ , MIF and IL-6.
- E.A. 12. (Original) The method of Claim 11 wherein the second agent is an antibody to TNF or an IL-1 receptor antagonist (~~IL-1ra~~).
13. (New) A method for treating inflammatory bowel disease, comprising administering an amount of an HMG1 antagonist effective to inhibit the inflammatory cytokine cascade, wherein said HMG1 antagonist is an antibody that binds to HMG1 and inhibits the interaction between HMG1 and RAGE.

14. (New) The method of Claim 13 further comprising administering a second agent in combination with the HMG1 antagonist, wherein the second agent is an antagonist of an early sepsis mediator.
15. (New) The method of Claim 14 wherein the second agent is an antagonist of a cytokine selected from the group consisting of TNF, IL-1 $\alpha$ , IL-1 $\beta$ , MIF and IL-6.
- E.A. 16. (New) The method of Claim 15 wherein the second agent is an antibody to TNF or an IL-1 receptor antagonist (~~IL-1ra~~).
17. (New) A method for treating systemic lupus erythematosus, comprising administering an amount of an HMG1 antagonist effective to inhibit the inflammatory cytokine cascade, wherein said HMG1 antagonist is an antibody that binds to HMG1 and inhibits the interaction between HMG1 and RAGE.
18. (New) The method of Claim 17 further comprising administering a second agent in combination with the HMG1 antagonist, wherein the second agent is an antagonist of an early sepsis mediator.
19. (New) The method of Claim 18 wherein the second agent is an antagonist of a cytokine selected from the group consisting of TNF, IL-1 $\alpha$ , IL-1 $\beta$ , MIF and IL-6.
- E.A. 20. (New) The method of Claim 19 wherein the second agent is an antibody to TNF or an IL-1 receptor antagonist (~~IL-1ra~~).
21. (New) A method for treating psoriasis, comprising administering an amount of an HMG1 antagonist effective to inhibit the inflammatory cytokine cascade, wherein said HMG1 antagonist is an antibody that binds to HMG1 and inhibits the interaction between HMG1 and RAGE.

22. (New) The method of Claim 21 further comprising administering a second agent in combination with the HMG1 antagonist, wherein the second agent is an antagonist of an early sepsis mediator.
23. (New) The method of Claim 22 wherein the second agent is an antagonist of a cytokine selected from the group consisting of TNF, IL-1 $\alpha$ , IL-1 $\beta$ , MIF and IL-6.
- E.A. 24. (New) The method of Claim 23 wherein the second agent is an antibody to TNF or an IL-1 receptor antagonist (~~IL-1ra~~).
25. (New) A method for treating cardiovascular disease, comprising administering an amount of an HMG1 antagonist effective to inhibit the inflammatory cytokine cascade, wherein said HMG1 antagonist is an antibody that binds to HMG1 and inhibits the interaction between HMG1 and RAGE.
26. (New) The method of Claim 25 further comprising administering a second agent in combination with the HMG1 antagonist, wherein the second agent is an antagonist of an early sepsis mediator.
27. (New) The method of Claim 26 wherein the second agent is an antagonist of a cytokine selected from the group consisting of TNF, IL-1 $\alpha$ , IL-1 $\beta$ , MIF and IL-6.
- E.A. 28. (New) The method of Claim 27 wherein the second agent is an antibody to TNF or an IL-1 receptor antagonist (~~IL-1ra~~).